GYNECARE X-TRACT Tissue Morcellator

ENGLISH

INSTRUCTIONS FOR USE

1.0 INTENDED USE

The GYNECARE X-TRACT Tissue Morcellator is intended for gynecologic, urologic and general surgical endoscopic use by trained professionals in hospital environments.

INDICATIONS:

Indicated for cutting, coring and extracting tissue in operative laparoscopy, including laparoscopic general surgical procedures, laparoscopic urologic procedures such as nephrectomy, and laparoscopic gynecologic procedures such as myomectomy and hysterectomy.

CONTRAINDICATIONS:

Contraindicated for use on vascularized tissue and as a dissecting tool. (Ovaries, fallopian tubes, myomata and other structures must be devascularized and dissected before morcellation.)

2.0 WARNINGS

2.1 Failure to carefully follow all applicable instructions may result in significant injury to the patient, physician or attendants and may have an adverse effect on the outcome of procedures performed.

2.2 The GYNECARE X-TRACT Tissue Morcellator is a precision instrument that must be handled with care by well trained and knowledgeable professionals. Carefully inspect the device and all associated equipment, instrumentation and cabling for damage prior to use. DO NOT attempt to operate this instrument if any damage is observed. Contact 1-877-ETHICON for replacement of damaged devices or cabling.

2.3 Use ONLY the GYNECARE Motor Drive Unit to connect to the GYNECARE X-TRACT Tissue Morcellator. Use of any other drive mechanism may result in failure of the Laparoscopic Morcellator to operate.

2.4 To prevent accidental injuries to the abdominal wall or similar structure, the tissue to be morcellated should be completely exposed before applying the device. In addition, it is recommended that a second pair of grasping forceps or a fixation instrument be used to prevent large pieces of tissue from uncontrollably moving. Slippage of the cutting tube can cause significant injury.

3.0 PRECAUTIONS

3.1 The physician must be thoroughly familiar with and carefully follow all manufacturer's instructions pertaining to this device and all associated accessories, equipment and instrumentation.

3.2 Procedures performed using the GYNECARE X-TRACT Tissue Morcellator, as with any endoscopic instrument, require adequate knowledge, training and preparation on the part of the physician/surgeon.

3.3 Exercise care when inserting or removing instrument. Use the retractable Blade Guard to prevent lateral injury to tissue from the sharp edged cutting tube. Insertion and removal should be performed under direct visual control at all times.

3.4 Follow local governing ordinances and recycling plans regarding disposal or recycling of the device.

3.5 The disposable GYNECARE X-TRACT Tissue Morcellator is shipped sterile. The product is intended for single use only. Attempts to clean and resterilize the device result in a risk of device malfunction and/or erroneous pathology specimen collection due to residual tissue in the morcellator.

3.6 CAUTION: The Tissue Morcellator blade guard should be used to prevent tissue damage even while the sharp cutting edge is stationary. Exercise caution while manipulating the Morcellator. Do not place cutter into contact with tissue which is not intended to be morcellated.

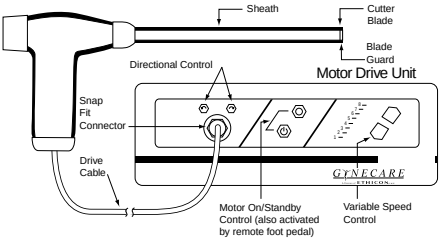
3.7 CAUTION: The use of a tissue extraction bag is recommended for the morcellation of malignant tissue or tissue suspected of being malignant and for tissue the surgeon may consider to be potentially harmful when disseminated in a body cavity.

4.0 DESCRIPTION AND FUNCTION

The GYNECARE X-TRACT Tissue Morcellator is comprised of two major components: the Tissue Morcellator and the Motor Drive Unit (MDU). The GYNECARE X-TRACT Tissue Morcellator is a disposable device which is provided sterile. It is essentially a rotating, cylindrical (tubular) razor blade, with a blade guard, which allows tissue to be grasped with a standard grasper type instrument extending through the central lumen of the device and then drawn up inside and past the rotating cutting edge and into the inner stationary sheath as the cutter cuts with a coring action. The cutter is powered by the GYNECARE Motor Drive Unit (MDU) via a flexible drive cable (see drawing). The physician can turn the GYNECARE X-TRACT Tissue Morcellator on and off via a foot pedal. The direction and speed of rotation are controlled on the face of the MDU by a nurse outside the sterile field.

The variable-speed, reversible MDU is an integral part of the GYNECARE X-TRACT Tissue Morcellator since it drives the rotation of the cutter/Morcellator at a controlled speed and torque. Thc GYNECARE Motor Drive Unit provides a user-selectable speed range at which to drive (rotate) the cutter/Morcellator. The torsional output of the motor is sufficient at all speeds to drive the cutter while cutting tough fibroid tissue. The direction of rotation of the motor is user-selectable.

The GYNECARE X-TRACT
Tissue Morcellator System



5.0 TECHNICAL SPECIFICATIONS

Specifications

Functional:	Speed Range	125 to 1000 rpm

6.0 DIRECTIONS

Note: To avoid inadvertent damage it is important to be thoroughly familiar with these instructions before handling instrument components.

6.1 UNPACKING AND GENERAL INSPECTION

6.1.1 Thoroughly inspect the outside of all shipping containers for indications of damage. Contact the shipping firm as necessary to resolve shipping damage.

6.1.2 Do not use the GYNECARE X-TRACT Tissue Morcellator if the package (sterile barrier) appears to be damaged or compromised.

6.1.3 Do not use the GYNECARE X-TRACT Tissue Morcellator past the expiration date.

6.1.4 Carefully remove components from shipping cartons and packing material. Inspect all components carefully to make certain that they have not been damaged in shipment. Contact 1-877-ETHICON with any questions or concerns.

6.1.5 Obtain a Return Goods Authorization Number from 1-877-ETHICON or representing company prior to returning any materials.

6.2 ASSEMBLY:

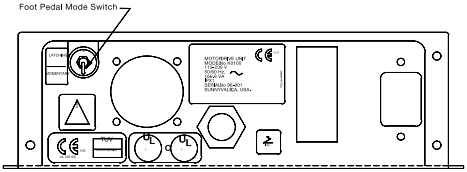
Connect the GYNECARE X-TRACT Tissue Morcellator Drive Cable to the GYNECARE Motor Drive Unit as follows:

6.2.1 The Drive Cable receptacle is located on the front of the Motor Drive Unit. Press down on the metal tab until it locks in place.

6.2.2 Remove the yellow cap from the proximal end of the drive cable on the GYNECARE X-TRACT Tissue Morcellator and carefully insert it into the receptacle on the MDU. Rotate it from side-to-side until it engages.

6.2.3 Press the surrounding plastic fitting in firmly until the metal tab releases and springs upward into place.

6.2.4 Ensure the foot pedal mode switch, located on the back panel of the Motor Drive Unit, is set to “Morcellator” mode.



Motor Drive Unit

6.3 OPERATION

6.3.1 The physician should read this entire manual with particular attention to the Warnings and Precautions sections and be thoroughly familiar with the use of the instrument prior to performing any clinical procedure.

6.3.2 DO NOT ATTEMPT TO SHARPEN OR MODIFY THE MORCELLATOR CUTTER. Bent or distorted cutters can result in patient or physician injury and equipment damage.

6.3.3 DO NOT ATTEMPT TO SHARPLY BEND THE MOTOR DRIVE CABLE in a diameter of less than 8 inches (20 centimeters). Sharply bent or kinked Motor Drive Cables may cause the Motor Drive Unit to overheat and stop. During a procedure, a minimum distance of 1.5 meters should be maintained between the Motor Drive Unit and the Morcellator to allow the Drive Cable to hang in a large arc with no bends or loops.

6.3.4 PREVENTIVE INSPECTION AND TEST:

Prior to operation:

6.3.4.1 The rotational speed may be increased in increments of 45 rpm by pressing on the upward-pointing yellow membrane switch. The number of lights in the switch will increase thus indicating that speed has been increased. The recommended speed for optimal Morcellator performance is 900 to 1000 rpm; this speed is indicated by the illumination of 2 lights on the speed switch.

6.3.4.2 If it appears that the Morcellator has stopped rotating during a procedure, check to ensure that all connections to the morcellator and MDU (both mechanical and electrical) are secure and that the drive cable has not wrapped up into a loop.

6.3.4.3 The Motor Drive Unit contains an internal switch to shut the unit off upon overheating. In this event, switch the main power switch (on the back of the unit) OFF and allow the unit to cool for several seconds before restarting.

6.3.4.4 If the drive cable wraps up and stalls the motor, press the pink stop button, reverse the direction of rotation with the direction arrow button, and intermittently run the motor in 1 second intervals until the drive cable unwraps and hangs freely with no loops.

6.3.5 OPERATIVE INSTRUCTIONS:

6.3.5.1 In laparoscopic procedures, a separate trocar/sheath assembly is normally used as the access port for the device to be introduced into the operative site. The GYNECARE X-TRACT Tissue Morcellator with obturator is subsequently inserted into the abdomen through the 15mm sheath under direct visual control.

6.3.5.2 In order to remove tissue, a 10mm claw forceps or similar instrument is inserted through the central lumen of the Morcellator and into the abdomen. The tissue to be extracted is then grasped and pulled up through the rotating Morcellator. In order to prevent injury to the abdominal wall, the tissue to be morcellated should be completely exposed before attempting to extract through the GYNECARE X-TRACT Tissue Morcellator. It is recommended that a second pair of grasping forceps or fixation instrument be used to help control tissue movement.

6.3.5.3 The high volume cutting capacity of the GYNECARE X-TRACT Tissue Morcellator makes it possible to extract large amounts of tissue in short periods of time.

7.0 TRANSPORT, STORAGE, CARE AND MAINTENANCE

The GYNECARE X-TRACT Tissue Morcellator components should be transported, stored and used at temperatures between -18°C and 55°C, 30 to 75% relative humidity, and -0.5 to +1.5 atmospheric pressure (507 to 1520 hPa). Care should be taken to avoid dropping or immersing the Motor Drive Unit in liquid.

8.0 CLEANING / REUSE

The GYNECARE X-TRACT Tissue Morcellator is a single-use disposable device and should NOT be cleaned and reused. Since the GYNECARE Motor Drive Unit is reusable many times, spilled fluids may be wiped clean from the outer case with a damp (not wet) cloth or sponge and soapy water after a procedure. BE CERTAIN THAT THE MOTOR DRIVE UNIT IS DISCONNECTED FROM THE POWER SUPPLY BEFORE CLEANING.

9.0 DISPOSAL

For proper disposal of the GYNECARE X-TRACT Tissue Morcellator, insert the obturator thru the center of the cutter and extend the blade guard over the cutting edge. The morcellator may now be disposed of safely in accordance with local governing ordinances and recycling plans.

10.0 WARRANTY AND TECHNICAL / CUSTOMER SERVICE

This device is warranted against defects in workmanship and material for one year from the date of delivery to the extent that GYNECARE will, at our option, replace, repair, or refund in full the purchase price of the device or any part thereof which in our opinion is defective, provided that the device has not been subjected to tampering, modification, or accidental abuse (such as dropping or immersion). A device that has been improperly used cannot be considered under this warranty.

WE MAKE NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, ANY WARRANTIES OF FITNESS OR MERCHANTABILITY, EXCEPT AS EXPRESSLY SET FORTH ABOVE. WE SHALL NOT BE LIABLE FOR ANY ANTICIPATED OR LOST PROFITS, INCIDENTAL DAMAGES, CONSEQUENTIAL DAMAGES, COSTS, TIME CHARGES, OR OTHER LOSSES IN CONNECTION WITH THE DEVICE OR ANY REPLACEMENT PARTS THEREFORE OTHER THAN AS EXPRESSLY PROVIDED BY SPECIFIC LAW.

If a manufacturing defect is found during a period of up to one year from date of delivery, GYNECARE will repair or replace the device or replace any defective part thereof without charge to the purchaser; however, GYNECARE's obligation thereunder does not include the cost of transportation which must be borne by the customer. GYNECARE assumes no responsibility for damage in transit, and any claims for such damage should be presented to the carrier.

11.0 CAUTION

Federal (U.S.A.) Law restricts this device to sale by or on the order of a physician.

MANUFACTURER:
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Meaning of Symbols; Motor Drive Unit & Labels